

# Exhibit C

John R. Miklos, M.D.

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC  
REPAIR SYSTEM PRODUCTS  
LIABILITY LITIGATION

MASTER FILE NO.  
2:12-MD-02327  
MDL 2327

THIS DOCUMENT RELATES TO THE  
FOLLOWING CASES IN WAVE 1 OF MDL  
200:

JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE

ALFREDA LEE, et al., V. ETHICON, INC., et al.  
CIVIL ACTION NO. 2:12-cv-01013

SUSAN THAMAN V. ETHICON, INC., et al.,  
CIVIL ACTION NO. 2:12-cv-00279

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DEPOSITION OF  
JOHN R. MIKLOS, MD

April 8, 2016

10:52 a.m.

3575 Piedmont Road, NE  
Atlanta, Georgia

Heather Brown, RPR  
CCR-4759-4284-5258-1376

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1 Q. Do you still do a fair amount of laparoscopic  
2 procedures?

3 A. Absolutely.

4 Q. Would it be fair to say that the most influential  
5 variable in outcomes is the skill set of the surgeon?

6 A. Repeat the question, please.

7 Q. Sure. Would it be fair to say that the most  
8 influential variable affecting patient outcomes following  
9 surgery is the skill set of the surgeon?

10 A. I've never looked at that scientifically, but I  
11 believe that the skill of the surgeon plays one of the most  
12 important roles, yes.

13 Q. For instance, I know you are well-published and have  
14 a good reputation -- a very good reputation in laparoscopic  
15 surgical procedures. There are other surgeons who have access  
16 to those same laparoscopic trocars, you know OR set up, et  
17 cetera, but who do not have results as good as yours as  
18 published. What would you attribute that to, if anything,  
19 beyond the skill set of the surgeon?

20 A. Oh, multiple things. It's obviously education,  
21 training, commonsense, pragmatism, logic doing surgery. I can  
22 even equate it back to just how I was raised. But that being  
23 said, it also requires that -- well, let me put it this way: I  
24 have the great fortune of operating all over the world, and  
25 having the appropriate equipment is extremely important, too.

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1 agree obviously that it wasn't defective in some surgeons  
2 hands, true?

3 A. No. I won't agree to that. Defective design entails  
4 that you're not going to get -- defective design to me means  
5 that your risk outweighs the benefit with the product that's in  
6 your hands. I personally used it on a cadaver and on the first  
7 cadaver I used it on, I knew it was defective. Number 1, the  
8 razor blade, exactly what it is, the insertion tip, is  
9 unprecedented. I have been around in courses, in operating  
10 rooms, and have used all other types -- many other types -- of  
11 TVTs, TOTs, TVT-Os and they're all the same. They're long,  
12 narrow tubes that are cylindrical, cylindrical with a conical  
13 tip usually. Now all of a sudden, you have a new device that  
14 has a razor blade on it and you're asked to make a 1 centimeter  
15 incision and you're delivered this razor blade device that cuts  
16 through tissue, including urethra potentially, bladder  
17 potentially, and periurethral tissue.

18 Not only is it unprecedented and it destroys  
19 tissue and increases -- we know with that type of trauma it's  
20 going to increase scar tissue. Now, the actual release of the  
21 device, the releasing mechanism was horrendous and this is  
22 documented in the internal documents. It was said that day in  
23 the operating room on the cadaver. Vince Lucente agreed with  
24 me. He said, yeah, they need to redo it, but there's secrets  
25 of doing it. You gotta jiggle it. If you jiggle it -- and we

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1 see this even -- Hinoul even says it. Hinoul was their  
2 employee and he's writing this stuff in his paper. He's saying  
3 well, yeah, it could dislodge. Yeah, you jiggle it, you're  
4 dislodging the insertion tip.

5 Q. Right.

6 A. That's the next problem, the insertion tip has never  
7 been proven. Then you have this polysorb which is vicryl -- is  
8 poly-p-dioxanone, basically it's an absorbable material that  
9 has never been utilized before in the pelvic floor.

10 And finally, the device itself, when you get  
11 that device it was unlike any other device. When you got a  
12 TVT, they gave you everything you needed almost. Everything  
13 that you can use to apply the mesh. This, you actually had to  
14 attach a straight hemostat to it or a needle driver.

15 Q. Needle driver.

16 A. Which was ridiculous because people were actually --  
17 you can't control the trajectory of where this needle tip is  
18 going and then trying to get the release and insert and stay.  
19 And then the last thing is because you're pushing it in, you're  
20 not pulling it through like the TVT or TOT or the Abbrevio, you  
21 have difficulty adjusting the tension because you're just  
22 pushing. How tight is tight? So it's a completely defective  
23 design.

24 Q. So it's your opinion that it's defective because of  
25 those attributes, but we can agree that even with those

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1 attributes to which you find objectionable or defective,  
2 surgeons still can get good results with TVT-Secur as evidenced  
3 by peer reviewed public literature you are aware of, correct?

4 A. Absolutely. You can kill a rabbit with a stone, too,  
5 but not too many people can do it.

6 I mean, the bottom line is when you produce a  
7 product, you need a product that is reproducible -- gives you  
8 reproducible efficacious results with minimal morbidity that  
9 you can put in your surgeons' hands. Here we see a product  
10 that was not -- they couldn't reproduce the results. So  
11 there's some people that can do it, but this is not to the  
12 benefit of the patient. If we go and look at J & J's credo,  
13 which I haven't looked at in a while, patient care and the  
14 responsibility to the patient is first and foremost. This  
15 is -- I've got to be honest with you, honestly, if this is your  
16 mom, you wouldn't give her a TVT-Secur. You would not.

17 Q. So you're aware that they received complaints from  
18 some surgeons on Secur and they did various investigations and  
19 did -- came out with key technical points on TVT-Secur?

20 A. Yes. They received some complaints from some  
21 surgeons, yes.

22 Q. I mean it's in the Quality Board minutes that you've  
23 looked at and that I've looked at, correct?

24 A. The problem is -- here's what's amazing to me: I  
25 never knew -- I was a leader for TVT, I never knew there was a

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1 STATE OF GEORGIA:

2 COUNTY OF GWINNETT:

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4 I hereby certify that the foregoing transcript was  
5 reported, as stated in the caption, and the questions and  
6 answers thereto were reduced to typewriting under my direction;  
7 that the foregoing pages represent a true, complete and correct  
8 transcript of the evidence given upon said hearing, and I  
9 further certify that I am not of kin or counsel to the parties  
10 in the case; am not in the employ of counsel for any of said  
11 parties; nor am I in any way interested in the result of said  
12 case.

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Heather Brown, RPR

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CCR 4756-4284-5258-1376

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